SEP 16 2002

510(k) Number: K021983
UltiGuard Home Insulin Syringe Dispenser and Sharps Container

510(k) Summary of Safety and Effectiveness

1) The submitter of this submission is:

Ulti Med Inc.
287 E. Sixth Street
St. Paul, MN 55101
Telephone (651) 291-7909
Fax (651) 291-7074

The contact person is:

Charles W. Erickson
e-mail: c.erickson@ulti-care.com

On this 10th day of September, 2002.

2) The trade name of the package shall be "Ulti Guard Home Insulin Syringe Dispenser and Sharps Container".

3) The Ulti Guard *Home Insulin Syringe Dispenser and Sharps Container* has the comparable intended use as the pre marketed Becton Dickinson *Home Sharps Container.*

4) The Ulti Guard *Home Insulin Syringe Dispenser and Sharps Container* has been tested with acceptable results for Impact Resistance, Puncture Resistance, Leak Resistance Sharps Access and Stability.

5) Ulti Guard Home syringe container contains 100 UltiCare insulin syringes. Syringes can be selectively removed as needed, and used syringes conveniently deposited back into the top of the container for safe storage. Ulti Guard syringes and container are single use only.

6) The intended use is for the storage and disposal of insulin syringes.

7) The UltiGuard Home syringe container differs from the predicate device as the disposal container is sold with the syringes. As syringes are removed and used, the container has the purpose of safely storing the used syringes. This promotes the convenient and safe disposal of used syringes in the home.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2002

Mr. Charles Erickson
President
Ulti Med, Incorporated
287 East Sixth Street
Saint Paul, Minnesota 55101

Re: K021983
Trade/Device Name: Ulti Guard Home Insulin Syringe Dispenser and Sharps Container
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: August 28, 2002
Received: August 29, 2002

Dear Mr. Erickson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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UltiGuard Home Insulin Syringe Dispenser and Sharps Container

Indication of Use Statement

The Ulti Guard Home Insulin Syringe Dispenser and Sharps Container by Ulti Med Inc. is intended to be used to transport, store and dispense insulin syringes in the home. After use the used syringe can be placed back into the container for safe storage and eventual disposal according to local regulations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K021983